



# Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

3380 Americana Terr, Suite 320, Boise, ID 83706

### **Individual DEA Registration Required**

First-year family practice resident physicians are not licensed by the Idaho Board of Medicine and are therefore not permitted to register with the Idaho Board of Pharmacy and Drug Enforcement Administration (DEA). Pursuant to Idaho Code §37-2717 the Board of Pharmacy cannot issue an Idaho controlled substance (CS) registration unless the practitioner currently holds a valid, unrevoked, and unsuspended license. 21 CFR 1301.01 requires every person who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any CS to obtain DEA registration. First-year resident physicians do not possess a valid Idaho medical license for the jurisdiction in which they practice and are not eligible for DEA registration or an Idaho CS registration. If your pharmacy is filling prescriptions for family practice physicians who are using another practitioner's DEA registration number, the prescription is not valid. Any practitioner, regardless of his or her residency, using another individual's DEA registration is in violation of both state and federal law. Please call the Board of Pharmacy office if you have additional questions regarding this matter.

### **Future Board of Pharmacy Meetings**

Meetings are subject to change; please verify on our Web site before attending.

3/7/08: Doubletree Club hotel, 475 West Parkcenter Blvd, Boise, ID

5/29/08: Coeur D'Alene Resort, 115 South Second St, Coeur D'Alene, ID

During legislation and rule review, topics expected to be discussed include: (1) long-term care; (2) technician/intern/clerk issues; (3) pharmacotherapy; (4) multiple Schedule II prescriptions; (5) pharmacy inducements; (6) days supply; (7) fees and schedules; and (8) tamper-resistant prescription pad requirements

Public comment is welcomed, both at the meetings and in oral or written form, addressed to the Board of Pharmacy office.

### **Future Law Continuing Education Programs**

The following scheduled continuing education (CE) programs will satisfy the annual requirement as mandated by rule No. 134.02: "One clock hour (0.1 CEU) must be Board of Pharmacy approved jurisprudence (pharmacy law) programs." Subject to change; please verify dates, times, and locations on the Board of Pharmacy Web site prior to attending.

4/3/08: Ketchum: St Luke's Wood River Medical Center, 100 Hospital Dr

4/4/08: Twin Falls: St Luke's Magic Valley Medical Center, 650 Addison Ave West

4/6/08: Boise: Idaho Society of Health-System Pharmacists Spring Meeting, St Luke's Regional Medical Center

4/13/08: Post Falls: Idaho State University (ISU) Spring CE Program, Red Lion, 414 E 1<sup>st</sup> Ave

4/14/08: Lewiston: St Joseph's Regional Medical Center, 415 6<sup>th</sup> St

4/15/08: McCall: Memorial Hospital, 1000 State St

4/27/08: Boise: ISU Spring CE Program, Hilton, 7699 Spectrum St

5/18/08: Pocatello: ISU Spring CE Program, Holiday Inn, 1399 Bench Rd

6/1/08: Coeur D'Alene: ISPA's NW Convention, Coeur D'Alene Resort, 115 S 2<sup>nd</sup> St

### **Multiple Schedule II Prescriptions**

Effective December 19, 2007, DEA amended a regulation to allow practitioners to provide an individual patient with multiple prescriptions for a specific Schedule II CS, written on the same date, to be filled sequentially. The change will allow patients to receive, over time, up to a 90-day supply of the prescribed CS. The Controlled Substances Act does not permit the refilling of Schedule II CS; a new prescription must be issued for each quantity of the substance. Idaho pharmacy rule No. 458 states: "No person shall fill a prescription for a controlled substance listed in schedule II unless the prescription is **tendered** to him or her before the thirtieth day following the date of issue." Thus, in accordance with the DEA and Idaho rule, Idaho pharmacies may fill Schedule II prescriptions, which are **tendered** to the pharmacy within 30 days of issuance, past the 30-day mark.

### **Manufacturers Agree to Restrict Distribution of Methadone**

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria. The 5 mg and 10 mg formulations, indicated for treatment of pain, will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not Food and Drug Administration approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

### **2008-2009 Renewal Season**

Renewed licenses or registrations of all pharmacists, pharmacies, wholesale drug distributors, manufacturing drug outlets, non-pharmacy drug outlets, nursing homes, hospitals without a pharmacy, veterinary legend drug outlets, preceptor sites, veterinary drug technicians, and pharmacy technicians are due on June 30. Please ensure the Board office has your current mailing address. Renewal forms will be online toward the end of April 2008. Pharmacists, please be aware that when you sign your renewal you are certifying that you have completed the appropriate CE. Do not send your CE documents to the office; you will be notified if you are audited and will be required to send documentation at that time. If you have questions regarding your renewal you may contact Ellen at [Ellen.Mitchell@bop.idaho.gov](mailto:Ellen.Mitchell@bop.idaho.gov) or Laura at [Laura.Poulsen@bop.idaho.gov](mailto:Laura.Poulsen@bop.idaho.gov).



## **NABP Testifies in Support of Proposed BTC Class of Drugs**

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

## **A Rose by Any Other Name . . . Might Be Safer**



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**<sup>®</sup> **Community/Ambulatory Edition** by visiting [www.ismp.org](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://www.ismp.org)) for links with USP, ISMP, and FDA. Or call 1-800-23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor<sup>®</sup>) and lovastatin (Mevacor<sup>®</sup>). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drug names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex<sup>®</sup> (pain treatment) connotes "celebration" and Halcion<sup>®</sup> (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.<sup>®</sup> Web site [www.med-errs.com](http://www.med-errs.com) and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals



and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl<sup>®</sup> renamed Razadyne<sup>™</sup>, (see *ISMP Medication Safety Alert!*<sup>®</sup> *Community/Ambulatory Edition*, Volume 4, issue 5, May 2005, **Reminyl<sup>®</sup>/Amaryl<sup>®</sup> Your Reports at Work.**) may “smell” safer, and therefore “sweeter.” Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem<sup>™</sup>. Stay tuned.

## **FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules**

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with “illegible or incomprehensible” labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

## **FDA Posts Drug Safety Newsletter, Labeling Changes**

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at [www.fda.gov/cder/dsn/default.htm](http://www.fda.gov/cder/dsn/default.htm) and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm).

## **NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies**

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services’ (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, [www.nabp.net](http://www.nabp.net).

## **FDA Acts to Ensure Thyroid Drug Potency until Expiration**

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at [www.fda.gov/cder/drug/infopage/levothyroxine/default.htm](http://www.fda.gov/cder/drug/infopage/levothyroxine/default.htm).

## **FDA Reform Law Provides for Establishment of Tracking Standards**

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

## **2008 Survey of Pharmacy Law Now Available**

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites<sup>™</sup> accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, “Pharmaceutical Compounding – Sterile Preparations.”

To order the *Survey*, visit [www.nabp.net](http://www.nabp.net) and download an order form; the cost is \$20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma L.P. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at [custserv@nabp.net](mailto:custserv@nabp.net).

## Idaho State University College of Pharmacy Celebrates 90<sup>th</sup> Anniversary

The ISU College of Pharmacy turns 90 in 2008 after having served as Idaho's only institution of pharmacy education in the state since 1918. More than 3,500 alumni began their professional pharmacy training at the college. To commemorate the 90<sup>th</sup> anniversary, the ISU College of Pharmacy will host an all-class reunion on August 1-2, in Pocatello. To meet the interests of all alumni, several events are slated, including golfing, swimming, and a picnic at the Pocatello Aquatic Center and Ross Park; tours of the college and campus; and a Friday evening event icebreaker social at Leonard Hall. The highlight of the weekend is a banquet at the L.E. and Thelma E. Stephens Performing Arts Center's Marshall Rotunda. For additional information, go to the college Web site at [www.pharmacy.isu.edu](http://www.pharmacy.isu.edu) or call Andrew Gauss, director of college relations, at 208/282-3393.

### Fiscal Year 2008 Disciplinary Action, to Date

- 8/2/07: T.B., RPh, five-year probation, \$200 fine, \$150 costs for diversion.  
8/2/07: C.P., MD, surrender of CS Registration for diversion.  
8/2/07: M.P., DDS, ordered to report.  
10/26/07: D.T., RPh, \$5,000 fine for filling invalid Internet prescriptions.  
10/26/07: A.K., RPh, \$5,000 fine for filling invalid Internet prescriptions.  
10/26/07: J.S., RPh, one-year suspension, \$250 fine, \$600 costs for diversion.  
10/26/07: P.B., NP, one-year probation, \$250 fine, \$1,500 fees, for record-keeping violations.  
10/26/07: K.B., NP, Surrendered CS Registration: obtaining by fraud.  
10/26/07: J.S., NP, Surrendered CS Registration for misuse.  
1/4/08: K.A., RPh, five-year probation, \$250 fine, \$300 costs for impairment.  
1/4/08: A.K., RPh, five-year probation, \$500 fine, \$500 costs for record-keeping violations.  
1/4/08: W.F., RPh, \$350 fine for allowing a pharmacy technician access to a pharmacy in the absence of a pharmacist.  
1/4/08: J.H., pharmacy technician, \$150 fine for accessing a pharmacy in the absence of a pharmacist.

### Reporting of Illegal Activity

Idaho Code §37-2734 (a) states: "It is unlawful for any person knowingly or intentionally . . . (3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge."

Idaho Code §54-1732 (3) (f) states: "It is unlawful to: (1) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by fraud, deceit, misrepresentation or subterfuge; by the forgery or alteration of a prescription, drug order, or of any written order; by the concealment of a material fact; or by the use of a false name or the giving of a false address." Pharmacy staff identifying this illegal activity should report it to the local law enforcement agency having jurisdiction in their area. Reporting this activity to the Board of Pharmacy staff can initiate a fax alert, warning other pharmacies, but the Board of Pharmacy's jurisdiction does not extend past its registrants and licensees.

### Duty to Report Change in Employment

Rule No. 156.02 states: "Any change in pharmacist or extern/intern employment must be reported to the Board within five (5) days." This duty to report is placed upon the "pharmacy employer." Rule 156.04 states: "Every part of the establishment coming under the regulation of the pharmacy laws shall be under the full and complete control of such pharmacist manager." Thus, it is both the duty of the pharmacist manager and the pharmacy employer to notify the Board of such employment changes within five days. Failure to follow rule No. 156 is a citable offense.

### Donald C. Tolley, RPh

The Board received the sad news of Donald C. Tolley's death this week. Some of you will remember Don as a friend, pharmacist, and a member of the Board of Pharmacy. Don graduated from ISU College of Pharmacy in June 1952 and received his pharmacist license the following month. He served the profession of pharmacy in the state of Idaho for over 50 years. Don was appointed to the Board by Governor John V. Evans in January 1983 to complete Llyn Lloyd's term when Mr Lloyd became the executive director of the Board. Don went on to serve the Board until 1995 when his second term expired. Don owned and operated Medical Clinic Pharmacy in Caldwell for many years. After he sold the pharmacy, he continued to do relief work at community pharmacies in the area. Don loved serving his patients and his community, and he did both very well. He will be greatly missed by all who knew him.

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